Guide to Revenue Optimization and Compliance for Pharmaceutical Manufacturers

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WHITE PAPER

Facing complex and challenging market dynamics, the global pharmaceutical industry must consider impactful changes to revenue strategy and execution. This guide explores these market pressures and associated impacts on how pharmaceutical manufacturers price, sell, and distribute their products. We also share our perspective on how manufacturers can gain a competitive advantage by automating their processes and using data and analytics to optimize revenue and ensure contract and regulatory compliance.

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Market landscape for pharma revenue execution

One of the most significant market dynamics impacting drug manufacturers is uncertainty related to the regulatory environment. Governments worldwide, driven by consumer pressure, are seeking to contain healthcare costs. Regulatory proposals across the globe come and go, but with each proposal, manufacturers need to evaluate the potential impact and changes required to comply with the new regulations – which is often a time-consuming and costly effort.

Already, many regulations must be considered when manufacturers make decisions about drug pricing and distribution. The added burden of an unpredictable, dynamic regulatory landscape means manufacturers must adapt quickly to new regulations. Even simple non-compliance scenarios under current laws can lead to substantial fines and penalties. Consequences can be dramatically more severe if non-compliance happens with a VA hospital. In that scenario, penalties can include revocation of the manufacturer's ability to treat government patients. And in cases of extreme and repeated non-compliance, the government may delist the manufacturer's products, causing massive revenue impact and turmoil. Monitoring and complying with existing regulations, while looking ahead to potential future legislation, makes regulatory compliance a significant burden.

One driver for changing regulations is the increasing demand for price transparency. Governments, consumer advocacy organizations, and consumers are demanding to understand how drugs are priced and why some drugs are more expensive in some regions than others. This demand is unlikely to go away, and drug manufacturers must prepare for how they will increase visibility into their pricing strategies. This is difficult, given the complexity of global pricing and tendering; however, it is critical to maintaining public trust and credibility, in addition to regulation adherence.

At the same time, pharmaceutical research, production, and distribution costs will likely rise. Manufacturers must account for these cost increases, while figuring out how to handle the pressure to reduce out-of-pocket costs to patients.

23

As of January 1, 2024, 23 states have passed drug price transparency laws, and legislation is pending in two more.[1]

70%

In 2021, 70% of the $11.8 billion spent by Medicare Part D on 45 generic drugs was gross profit for pharmaceutical supply chain intermediaries.[2]

[1] "State Pricing Transparency Alert: More Changes Are Coming." Model N.

[2] Noah Tong. "Pharmacies and wholesalers, not just PBMs, rely on spread pricing." Fierce Healthcare. October 20, 2023.

Additional market forces impacting pharmaceutical manufacturers include:

- Market consolidation through mergers and acquisitions resulting in revamped systems, processes, and contracts
- Broader adoption of contract manufacturing to meet rising global demand, which increases supply chain complexity
- Ever-changing global referencing relationships, which impact global pricing and market launch strategies
- Demand for value-based contracts, which drives new business models that must be implemented across the selling process

Together, these factors increase the complexity and cost of doing business in the pharmaceutical industry. The process of manufacturing, selling, and distributing drugs is already complicated; market pressures only add to the intricacies involved in success and market leadership.

Organizations that expertly employ people, processes, technology, and data to efficiently address these challenges have a distinct competitive advantage. These elite organizations can confidently comply with new regulations, successfully manage margins through a complex matrix of pricing requirements and contracts, and meet transparency requirements.

Revenue optimization evaluation

What is the appropriate way to create the capabilities needed to respond to this dynamic market? The first step is evaluating the current state of your organization by answering a series of questions related to your existing people, processes, technology, and data capabilities.

To **assess** your people, consider:

- Are your employees trained and organized well enough to respond to new and evolving industry challenges?
- How disruptive is it when key individuals leave?
- Do you struggle to find qualified talent or experts to support your revenue management program?
- Do you have the right skills for handling the complexities of commercial operations, compliance, and data analysis?

For **processes**, ask:

- What repeatable processes are currently in place?
- Are current processes adaptable to the challenges of the market?
- How will you comply with proposed regulations?
- What do you need to do differently? How will you ensure those changes are successfully adopted?
- How quickly can you roll out new pricing strategies?

For **technology**, examine:

- What percentage of your processes is automated today, and what is still manual?
- Are current systems adaptable to changes?
- How long will it take and how much will it cost to change systems to comply with new regulations?
- Is there an end-to-end system of record? If not, how are siloed systems integrated into the process?
- Do processes and systems differ across operating regions and business units?

And finally, for **data and analytics**, contemplate:

- Are your revenue management systems isolated from central data hubs, master data systems of record, and other third-party data software solutions?
- Does your team struggle to gather meaningful and timely insights from your systems and processes?
- Are you sifting through too many reports and data sources, which makes it difficult to identify anomalies and trends?
- Is your team spending their time researching customers and matching industry identifiers and membership rosters?

The list of questions is extensive and may include more areas to explore that are unique by company. Only through judicious and thorough evaluation of your current state can you minimize your risk and maximize your revenue.

Once these questions have been adequately answered, you should develop a plan to address problem areas and create an approach that puts you on a path to success. Without taking a dispassionate look at your organization, you will not be able to respond to the challenges you're facing. By going through this process, you will be best positioned to lead the market.

6%

Pharmaceutical manufacturers unknowingly leak as much as 6% of their revenue due to ineffective systems. **That's $60 million for every billion dollars of revenue.**

How to become a revenue-optimized organization

It can be daunting to envision solving issues at the nexus of people, processes, technology, and data to address market dynamics. With the right end state in mind, you can systematically build an approach that will streamline processes, enable people, and leverage end-to-end software designed specifically to help the pharmaceutical industry meet the challenges of the changing market landscape.

In this desired state, you can:

- Execute your pricing strategies to ensure they meet government pricing requirements.
- Seamlessly integrate pricing into enterprise resource planning (ERP) and customer relationship management (CRM) systems and deliver data via an electronic data interchange to wholesalers.
- Roll out new and updated pricing on a global scale, enabling your sales staff to increase market share while maximizing profits.
- Improve accuracy of rebates, fees, and chargebacks to ensure compliance and avoid overpayments.
- Deliver data to downstream systems and departments, improving accuracy for financial reporting, revenue recognition, and performance trending and analysis.

A strategic and unified solution that establishes accuracy, confidence, compliance, and a single version of truth is critical in today's environment. By removing the silos of management in global reference pricing, tendering, payers and provider contracting, government pricing, and Medicaid rebates, you can gain clarity. This vision includes actionable strategies to prevent as much as 6% of revenue from leaking due to ineffective systems and processes.

Best practices for revenue optimization

Optimizing revenue across the pharmaceutical supply chain is a critical capability in today's dynamic market – one that involves succeeding in four key areas of revenue management:

1. Enhancing revenue execution.
2. Maximizing global revenue.
3. Ensuring regulatory compliance.
4. Driving decision-making with robust data and analytics capabilities.

Each of these areas can be specialized, but taken together, they are highly strategic to an organization.

1. Enhancing revenue execution

Ensure compliance with payer agreements

Managing the complex and fast-changing payer pricing and contracting landscape is an ongoing challenge. Manufacturers often have tens of hundreds of contracts in place with various payers, for both commercial and Medicare Part D. Without consistent, accurate, and reliable data, it can be nearly impossible to clearly determine which prescriptions are eligible for rebates.

Navigating the complex requirements for formulary, market share, and price protection calculations requires a comprehensive approach – one that combines technology, data, and proven processes. To optimize revenue and ensure compliance with your payer agreements, consider:

- Using a single platform to handle all aspects of contracts and pricing management, formulary management, and plan management
- Leveraging preapproved templates and clauses (value-based and traditional) for better governance and reduced risk exposure
- Relying on automation to effectively validate the sheer volume of prescription and medical benefits data, prevent costly errors and late fees, and accurately pay rebates only on dispensed products for the rate they're eligible for
- Developing an automated workflow that allows contract, validation, and rebate analysts to monitor, investigate, and identify suspect claim lines in a timely and efficient manner

On average, pharmaceutical organizations pay 25 to 31% of their revenue in rebates with heavy penalties for late payments. This makes accurate and timely chargeback validation, calculation, and settlement crucial to success. Script-level validation and claims-level detail analysis enable your teams to:

- Resolve the errors and ambiguity of payer data in processing managed care, Medicare, Medicaid, TRICARE, and coverage gap rebates.
- Enforce terms of agreements and ensure that rebates are only paid on eligible prescriptions.
- Generate insights into contract performance and compliance.
- Prevent duplicate discounts associated with the 340B Drug Pricing Program.

Reduce risk with commercial contracts

Managing group purchasing organizations (GPOs), integrated delivery networks (IDNs), health systems, and local hospital agreements – as well as administering pricing associated with government contracts, such as 340B and the VA – are often cumbersome, manual processes comprising spreadsheets and aging systems. However, if you're managing provider agreements manually, you could be missing opportunities to optimize revenue and ensure compliance with government programs. Real-time visibility and insights into your chargebacks; contracts and pricing; provider memberships; incentives, fees, and accruals; and tiered-pricing and Federal Supply Schedule compliance enable you to interact seamlessly with providers.

There is power in using the massive amounts of data available to address customer purchasing behaviors and manage price-tier commitments. Accessing clean, accurate data through a single provider management solution can enable you to reach greater than 98% clean first-pass rates in processing chargebacks, in accordance with Healthcare Distribution Alliance (HDA) best practices.

2. Maximizing global revenue

Optimize and protect product pricing across the globe

With an array of global market access challenges and several revenue growth drivers, you must be able to continuously adjust pricing by region throughout the entire product lifecycle and increase the speed of information exchange. Cost containment initiatives by payers, governments, and healthcare insurance organizations have created a challenging

business environment with controlled pricing, promotion of generic alternatives, and greater obstacles to bringing innovative drugs to market. Achieving global pricing excellence is now more important than ever if the industry is to remain viable while providing patients affordable access to medicines.

So, how do you execute innovative pricing strategies more effectively and protect prices globally? To gain visibility and control over the complexities of international reference pricing, launch sequences, and your published and nonpublished price lists, you need:

- Powerful technology that will support a variety of pricing simulations and controls
- A 100% accurate and validated price and reimbursement database
- Capabilities to automate and track multi-country launches and conduct pricing and sales forecasting

Win more tenders at the right price

As the complex bidding process becomes more competitive, global tenders must be managed efficiently to allow for planning and prioritization of tender response activities. Departments can shape and respond to tenders with limited resources – acting locally, but coordinating globally – by streamlining auditable approval workflows, tracking and analyzing tenders for continuous improvement, and developing best practices as the number of tenders grows.

Instead of relying on manual processes and disconnected spreadsheet-based tools, you need a unified solution that will enable you to plan, create, execute, track, and analyze global tenders. As it can be key to winning more bids, an integrated tender management application should provide:

- Visibility into global opportunities and the ability to generate winning strategies proactively
- A centralized view, clear workflows, and organized approval processes – all of which remove silos and increase operational efficiency
- A tender marketplace search that enables you to explore public marketplaces for new publications and convert them into tender opportunities
- Enhanced controls and insights that streamline the bidding process, promote cross-functional collaboration, and reduce risk of incorrect or missed submissions

3. Ensuring regulatory compliance

Comply with government pricing and reporting requirements

There is a growing demand for price transparency in the supply chain for drugs and biologics. Changes to the safe harbor rule may have been tabled, but the cry for price transparency continues, and most industry thought leaders expect new rules and mandates to come soon. In the meantime, complying with current regulations is imperative to avoid increased fines and preventable revenue loss. To manage risk and prepare for the unknown, consider proven systems, tools, and processes that deliver flexibility, agility, and innovation.

Cloud-based and data-driven revenue management solutions, comprised in a single system of record, will play an integral part in helping you transition to a new set of industry rules and standards and deal with the possible changes on the horizon. As you evaluate solutions, make sure the application you select offers regular and automated updates to incorporate changes to government pricing and reporting regulations, so you can stay in compliance while supporting every transaction, price, rebate, and adjustment.

Operationalize state drug price transparency reporting

While the federal government has been unable to curb the trend of wholesale acquisition cost (WAC) increases, many states have acted. Numerous states have passed legislation on price transparency, and others have proposed similar laws. While designed to help control pharmaceutical spend and generate a better understanding of the rationale for price increases, these rules differ greatly from state to state, creating administrative challenges.

To manage and meet the unique reporting needs of the vast set of state price transparency regulations, you need processes and tools that deliver visibility and automation. Reducing the manual burden of reporting enables you to mitigate risk of non-compliance and achieve operational excellence. For example, you can:

- Translate current and future legislative activity into tasks that can be configured and triggered based on each state's laws and regulations.
- Autogenerate reports based on a state's unique triggering events, using templates that address state-specific data fields, formats, and timelines.
- Analyze potential downstream impacts of future pricing or product events.
- Streamline cross-departmental visibility and collaboration with approval workflows, user-specific dashboards, and scheduled report calendars.

Process accurate and timely Medicaid claims

To help you navigate shifting regulations and quickly and accurately process Medicaid claims, all Medicaid data should live in a single source. A clear view into accurate data ensures immediate chargeback claim processing, thus reducing costly interest and government penalties. In the age of digital transformation, you cannot afford to rely on disparate legacy systems and integrations that can be slow and produce inaccuracies.

Furthermore, your Medicaid team should be spending time on high-value tasks like dispute resolution, instead of manually retrieving invoices and claims-level details from numerous portals and files.

Through aggregated or prescription-level utilization data validation and automated invoice retrieval, you can reduce the likelihood of overpayments and disputes in Medicaid rebates. Automated systems can help you differentiate Medicaid and commercial transactions and ensure accurate, timely claims remittances to federal and state governments – further reducing revenue leakage and potential for human error.

4. Driving decision-making with robust data and analytics capabilities

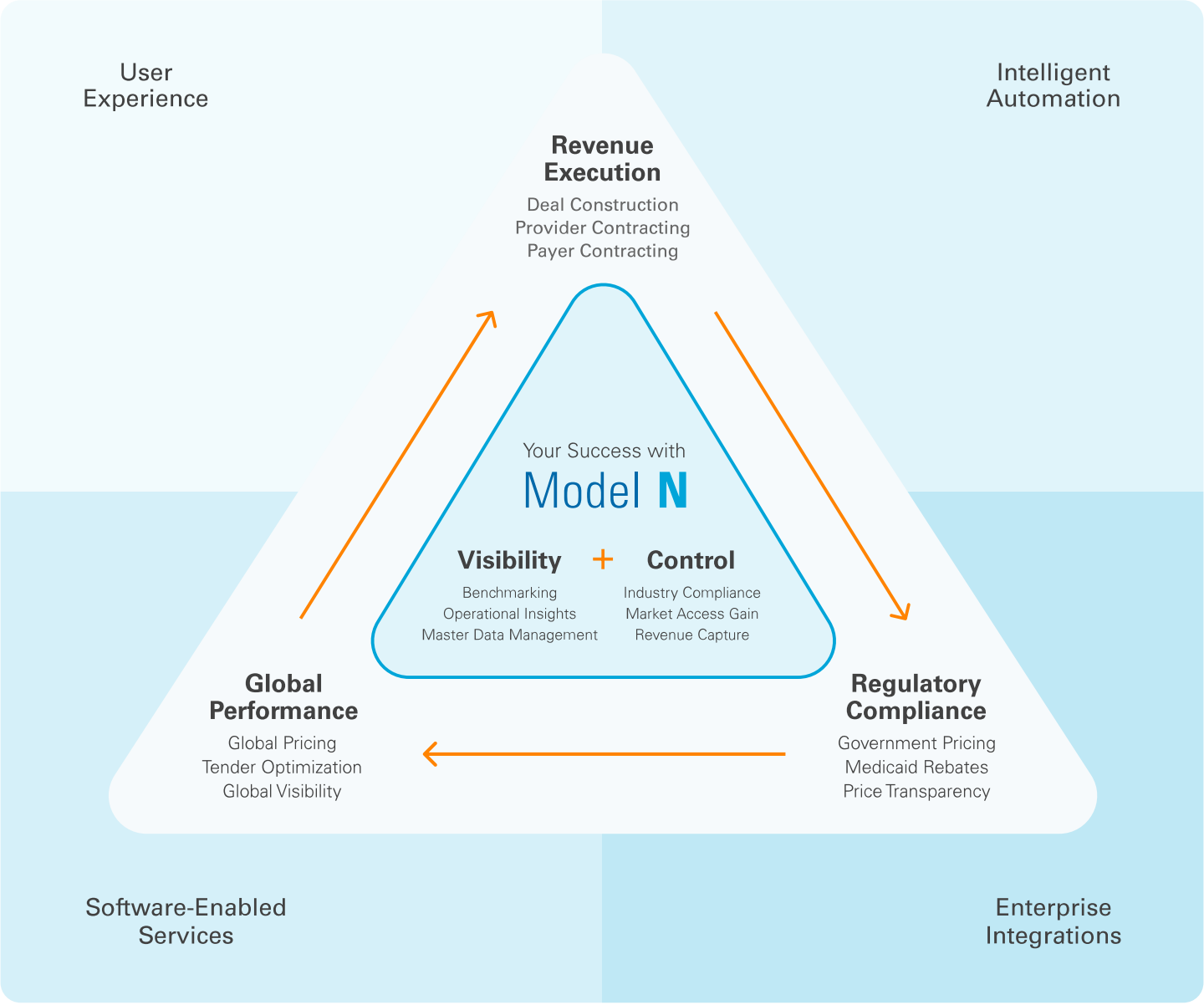
Consolidating your revenue management execution on a single, integrated platform puts powerful data at your fingertips. However, without an established data and analytics strategy, you may struggle to turn this data into actionable insights from which decisions can be based.

Whether you're using near-real-time APIs to feed data into existing data hubs, or you utilize packaged reports within your revenue management system, revenue management data helps eliminate data silos and streamline processes that rely on data spanning numerous disparate sources.

Examining the challenges with operationalizing analytics from revenue management data enables your entire organization to increase its understanding of key insights, including net pricing, health plan and payer performance, and sales trends. Additionally, streamlining research-intensive processes, such as customer master and membership matching and formulary analysis, allows your team to spend more time on analytics and value-added tasks.

End-to-end revenue execution

Integrated and transparent contract management, revenue operations, and risk mitigation functions are table stakes in today's dynamic pharmaceutical industry. It is no longer sufficient to knit together point solutions or rely on cumbersome spreadsheets. Errors and lost opportunities abound. Instead, an end-to-end system for revenue execution – one that incorporates people, processes, technology, and data and spans all functions in the revenue lifecycle – is required. This system must be robust, trusted, and designed for the unique challenges of the pharmaceutical industry.



Model N empowers pharmaceutical manufacturers to grow net revenue and market share, pay exactly what they owe the first time, and reduce regulatory compliance risk. Model N Revenue Cloud for Pharma automates processes within and across each function to become the system of record used to manage global pricing and tenders, contracts, chargebacks, and regulatory compliance. This intelligent platform integrates technology, data, analytics, and expert services to deliver deep insight and control over the complexities of commercial operations and compliance.

Regardless of where you are on the journey to revenue optimization, Model N can provide the right level of support – whether that be robust enterprise technology, business services powered by our purpose-built technology and delivered by industry experts, or a mix of both. It's this powerful portfolio of cloud software, expert services, and data and analytics that has helped customers prevent billions of dollars in revenue leakage and liabilities from non-compliance, and more importantly, enabled them to remain focused on bringing innovative and life-changing products to market.

Visit modeln.com for more information or contact us at **info@modeln.com** to receive a complimentary revenue execution assessment and ROI analysis from a pharmaceutical revenue management expert.

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